

## **REMARKS**

### **STATUS OF CLAIMS**

Claims 1-21, 23-38, and 61 are pending in the application and are rejected. Claims 1, 33, 37 and 61 have been amended. Claim 38 has been canceled. No new matter has been added. Support in the specification can be found at least in FIGS. 4-8 and the entirety of the specification as originally filed.

In light of the arguments and comments below, reconsideration and allowance of the present application are respectfully requested.

### **REJECTIONS UNDER 35 U.S.C. §112**

The Examiner rejected claims 1-21, 23-38 and 61 under 35 U.S.C. §112 as failing to comply with the enablement requirement. The Examiner states that it is unclear why the surfaces in FIGS 4 and 5 are inner and outer surfaces as opposed to, for example top and bottom or front and back. The Examiner has asked the Applicant to clarify or explain exactly what makes one of the surfaces inner and the other one outer. Applicants first note the Examiner refers only to FIGS. 4 and 5 while the application discloses other embodiments for a sensor holder, i.e. FIGS. 6-8. Other than the foregoing, Applicants concede the Examiner's point and have amended the claims to use the terminology "front" and "back," which is clearly supported by the FIGS. With the amendments to the claims, Applicants believe the enablement rejection has been overcome and respectfully request an indication of such in the next office action.

### **REJECTIONS UNDER 35 U.S.C. § 103(a)**

Claims 1-21, 23-29 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg, U.S. Patent No. 4,538,618 ("Rosenberg") in view of Rosen et al., U.S. Patent No. 4,228,805 ("Rosen"). Claims 30, 37 and 61 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenberg in view of Rosen and further in view of Riccitelli et al., U.S. Patent No. 5,166,990 ("Riccitelli"). Claims 31 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenberg in view of Rosen and further in view of Boggett et al., WO 98/20794 ("Boggett").

The Examiner states with regard to claims 1-21, 23-29 and 38 that Rosenberg discloses a blood flow sensor exposed on its longitudinal axis and is capable of contacting mucosal tissue, the flow sensor passing through a holder which has a passage therein through which the sensor passes and is flexible. The Examiner states that the device includes a PCO<sub>2</sub> sensor. The Examiner states Rosen shows a similar device to Rosenberg which determines the viability of tissue, which displays measurement values to alert the physician to the patient's status and thus it would have been obvious to modify Rosenberg to use such a display to provide more information as to the patient's condition. The Examiner states that claims 2-21 are rejected in that the device is capable of being positioned adjacent any of the mucosal surfaces recited and that with respect to claims 23-27 element 202 of Rosenberg is capable of being used to hold the sensor in position adjacent a mucosal surface and therefore meets the intended function of the positioning means. With respect to claims 28 and 29 the Examiner states the flow sensor of Rosenberg is laser-doppler or ultrasonic and that claim 38 is rejected because element 202 is at least partially flexible.

The Examiner states that claims 30, 37, and 61 are rejected as Riccitelli et al teaches that it is known to monitor pH and PCO<sub>2</sub> in the same intravascular measuring device. The Examiner states that claims 31 and 31 are rejected as Boggett et al teaches a microvascular monitoring device such as Rosenberg's, is known to monitor the rate of change of blood flow.

Applicants traverse the rejection and respectfully request reconsideration. Neither Rosenberg alone or in combination with Rosen and/or Ricitelli, disclose, teach or suggest a device for assessing systemic perfusion failure including blood flow and PCO<sub>2</sub> sensors wherein given a measured blood flow in an adjacent mucosal tissue that is substantially lower than a normal measured blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement the device derives the assessment of systemic perfusion failure in the patient. While it is true that Rosenberg discloses a blood flow sensor, blood flow alone is not necessarily indicative of perfusion failure. For example, a patient can have increased blood flow to a site or even normal blood flow to a site, but still have perfusion failure. Two measurements are necessary to assess perfusion failure, a mechanical factor such as blood flow and a metabolic

factor such as PCO<sub>2</sub>. Thus, Applicant is claiming a combination of elements that is simply not taught, suggested or disclosed by Rosenberg alone or in combination with Rosen and/or Rictelli.

Moreover, Rosenberg in combination with Rosen and/or Rictelli teach away from the present invention. Rosenberg teaches the measurement of local blood flow. In other words, Rosenberg focuses on microvascular monitoring. "According to a broad aspect of the present invention, there is provided a fluid flow detector for the non-invasive detection of the flow of a fluid through an object, which detector is particularly useful for microvascular monitoring . . ." Rosenberg, col. 1, lines 48-52. "The fluid flow detector illustrated in FIGS. 1 and 1a, and therein generally designated 2, is a microvascular monitor head for monitoring minute variations in the blood flow through skin or other tissue." Col. 2, lines 60-63. There are numerous other passages in Rosenberg that support Applicants contention that Rosenberg is directed solely to local blood flow and has nothing to do with perfusion of tissue, much less systemic perfusion. Therefore, given the disclosures of Rosen and Rictelli one of ordinary skill in the art would not be motivated to modify the Rosenberg device to measure a combination of elements such that the device derives an assessment of systemic perfusion failure. This would completely change the principle of operation of Rosenberg. MPEP §2143.01.

If an independent claim distinguishes over the prior art, so too do the dependent claims. MPEP §2143.03.

Applicants respectfully assert that all claims patentably distinguish over Nagai and request reconsideration.

#### ALLOWABLE SUBJECT MATTER

Applicants acknowledge and thank the Examiner for the indication of allowable subject matter in claims 33-36 if the enablement rejection is overcome. Applicants believe that with the amendments to the claims, the enablement rejection has been overcome.

Applicants submit that with the amendments and argument submitted herein all pending claims are allowable over the art of record and respectfully request withdrawal of the rejection under §103(a) and allowance of all claims.

**CONCLUSION**

All rejections having been addressed Applicants respectfully request that a Notice of Allowance be issued in this case. In the event a telephone call would expedite the prosecution of this application, the Examiner may reach Barbara Wrigley at (612) 607-7595. Applicants hereby petition for a three-month extension of time, the statutory period for response having expired on April 22, 2009 and this response being filed on or before July 22, 2009. The Commissioner is authorized to charge fees for any extension of time to Deposit Account No. 50-1901 (Reference 11242-320).

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Respectfully submitted,



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